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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/629,409	07/29/2003	Armin Altemus	ALTMUS.006A	7222	
20995	7590 02/24/2006		EXAMINER		
	KNOBBE MARTENS OLSON & BEAR LLP			DIXON, ANNETTE FREDRICKA	
2040 MAIN FOURTEEN			ART UNIT	PAPER NUMBER	
IRVINE, CA	92614		3743		

DATE MAILED: 02/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

			1.2
	Application No.	Applicant(s)	7
	10/629,409	ALTEMUS, ARMIN	
Office Action Summary	Examiner	Art Unit	
	Annette F. Dixon	3743	
The MAILING DATE of this communication  Period for Reply	on appears on the cover sheet w	ith the correspondence address	
A SHORTENED STATUTORY PERIOD FOR I WHICHEVER IS LONGER, FROM THE MAILI  - Extensions of time may be available under the provisions of 37 after SIX (6) MONTHS from the mailing date of this communical  - If NO period for reply is specified above, the maximum statutory  - Failure to reply within the set or extended period for reply will, b Any reply received by the Office later than three months after the earned patent term adjustment. See 37 CFR 1.704(b).	NG DATE OF THIS COMMUNI CFR 1.136(a). In no event, however, may a tion.  period will apply and will expire SIX (6) MOI y statute, cause the application to become A	CATION. reply be timely filed  NTHS from the mailing date of this communication. BANDONED (35 U.S.C. § 133).	
Status			
1)⊠ Responsive to communication(s) filed on	n 29 July 2003.		
	This action is non-final.		
3) Since this application is in condition for a closed in accordance with the practice up	· ·	·	
Disposition of Claims			
4) ⊠ Claim(s) <u>1-31</u> is/are pending in the application 4a) Of the above claim(s) <u>31</u> is/are withdrest 5) □ Claim(s) is/are allowed.  6) ⊠ Claim(s) <u>1-30</u> is/are rejected.  7) □ Claim(s) is/are objected to.  8) □ Claim(s) are subject to restriction	rawn from consideration.		
Application Papers			
9)⊠ The specification is objected to by the Ex	aminer.		
10)⊠ The drawing(s) filed on <u>7/29/2003</u> is/are:	a)⊠ accepted or b)☐ objected	d to by the Examiner.	
Applicant may not request that any objection			
Replacement drawing sheet(s) including the	•		
11) ☐ The oath or declaration is objected to by	the Examiner. Note the attached	d Office Action or form PTO-152.	
Priority under 35 U.S.C. § 119			
12) Acknowledgment is made of a claim for for a) All b) Some * c) None of:  1. Certified copies of the priority docu 2. Certified copies of the priority docu 3. Copies of the certified copies of the application from the International E * See the attached detailed Office action for	uments have been received. uments have been received in A e priority documents have been Bureau (PCT Rule 17.2(a)).	application No received in this National Stage	
Attachment(s)			
<ol> <li>Notice of References Cited (PTO-892)</li> <li>Notice of Draftsperson's Patent Drawing Review (PTO-93)</li> <li>Information Disclosure Statement(s) (PTO-1449 or PTO/Paper No(s)/Mail Date 7/29/2003.</li> </ol>	48) Paper No(	Summary (PTO-413) s)/Mail Date nformal Patent Application (PTO-152) 	

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## **DETAILED ACTION**

#### Election/Restrictions

- 1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - Claims 1-30, drawn to an Apparatus for Emergency Air Delivery, classified in class 128, subclass 205.13.
  - II. Claim 31, drawn to Method for Emergency Air Delivery, classified in class128, subclass 898.

The inventions are distinct, each from the other because of the following reasons:

- 2. Inventions Group I, Apparatus for Emergency Air Delivery, and Group II, Method for Emergency Air Delivery, are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the method could be practice by another apparatus using different steps, such as, the user putting the harness on first and then covering the nose and mouth of the patient.
- 3. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.
- 4. During a telephone conversation with Applicant's attorney, Mr. Michael H. Trenholm, on Wednesday, February 15, 2006, a provisional election was made without traverse to prosecute the invention of Group I, Apparatus for Emergency Air Delivery,

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Claims 1-30. Affirmation of this election must be made by applicant in replying to this Office action. Claim 31 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

## Specification

5. The use of the trademark VELCRO® has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

Examiner suggests Applicant use "hook and loop fastener" instead of the trademark VELCRO®. Further, Examiner specifically requests the addition of the registered trademark symbol in all instances of use.

## Claim Objections

- 6. Claim 1 is objected to because of the following informalities: Applicant recites "using their hands thereby freeing their hands to hold the mask." The recitation of "their" is indefinite. Examiner suggests Applicant modify the cited recitation to "the user's hands" or "the hands of the user." Appropriate correction is required.
- 7. Claims 4 and 8 are objected to because of the following informalities: Applicant recites "two bellows between their inner upper arms and torso." The recitation of "their"

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is indefinite. Examiner suggests Applicant modify the cited recitation to "the user's inner upper arms and torso" or "the inner upper arms and torso of the user." Appropriate correction is required.

- 8. Claims 6 and 10 are objected to because of the following informalities: In the independent claim, Claim 1, Applicant recites a respiratory system where a "user" provides compressed gas to a patient. However, in Claims 6 and 10, Applicant recites an "operator" who is providing care to the patient. The term "operator" lacks antecedent basis and renders the claims indefinite. Examiner suggests Applicant correct instances of the term "operator" to "user" or vice versa, to provide a unified recitation of the claimed invention. Appropriate correction is required.
- 9. Claim 30 is objected to because of the following informalities: Both Claim 30 and Claim 20 are dependent from Claim 19, and cite the same limitations. Appropriate correction is required.

## Claim Rejections - 35 USC § 112

- 10. The following is a quotation of the second paragraph of 35 U.S.C. 112:
  - The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.
- 11. Claims 11, 20, and 30 are rejected under 35 U.S.C. 112, second paragraph for the improper presence of a trademark or trade name in a claim. The use of trademarks or trade names is used to identify a source of goods, and not the goods themselves. If the trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of the 35

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U.S.C. 112, second paragraph. Ex parte Simpson, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. In fact, the value of the trademark would be lost to the extent that it because descriptive of a product rather than used as an identification of a source or origin of a product. Thus, the use of a trademark or trade name in a claim to identify or describe a material or product would not only render a claim indefinite, but would also constitute an improper use of the trademark or trade name. (MPEP § 2173.05(u))

12. Within the aforementioned claims, the trademark "VELCRO®" is used as a specific limitation and does not give way to generic "hook and loop fasteners," which are fully capable of performing as a locking device.

#### Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 14. Claims 12-17 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Sitnik (US 4,870,962).
- 15. **As to Claim 12,** Sitnik discloses a respirator comprising a face mask (16), a gas conduit (13), and a bellow system (1). (Please see Figures 1-3). Regarding the bellows (1), Sitnik discloses the bellows of the respiratory system to be fully capable of being

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compressed by the user to allow the exportation of exhaust gas via the output port and resiliently expandable to draw gas from the input port. Sitnik states, "the bag (1) is fitted with an air (and/or oxygen) intake valve (7) through which air is drawn during its self-inflation portion of the pump cycle. There is an air (and/or oxygen) outlet (8) through which air is expelled from the inner chamber of the bellows during compression."

(Please see Column 3, Lines 9-15). Specifically regarding the bellow shaped bag, Stinik discloses "its flat sides eliminate any tendency to roll away while being compressed, and thus enables an operator to compress it under his arm or knee, therein freeing both his hands for performing other tasks." (Please see Column 2, Lines 20-25). Regarding the conduit (13), Sitnik discloses the conduit to be interconnected with the output port and the mask. (Please see Figure 3).

- 16. **As to Claim 13,** Sitnik discloses a face mask (16), it is well known in the art that face masks are constructed to maintain contact with the face of the patient as to provide the greatest concentration of air or gas to the patient. As shown in Figure 3, Sitnik discloses a retaining edge on the face mask (16).
- 17. **As to Claim 14,** Sitnik discloses the bellows (1) to be capable of providing the operator with hands-free actuation. Thus allowing the operator to hold the face mask against the patient's face. Stinik discloses "its flat sides eliminate any tendency to roll away while being compressed, and thus enables an operator to compress it under his arm or knee, therein freeing both his hands for performing other tasks." (Please see Column 2, Lines 20-25).

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18. **As to Claim 15,** Sitnik discloses the tubing of the conduit (13) to be flexible and corrugated. (Please see Column 3, Lines 55-58).

- 19. **As to Claim 16,** Sitnik discloses a two way inhalation-exhalation valve (14) which serves as a coupling device that directs the gas flowing into and out of the mask (16). (Please see Column 3, Lines 55-58).
- 20. **As to Claim 17,** Sitnik discloses the gas flowing from the conduit (13) into the mask (16) is air or oxygen. Sitnik states, "the bag (1) is fitted with an air (and/or oxygen) intake valve (7) through which air is drawn during its self-inflation portion of the pump cycle. There is an air (and/or oxygen) outlet (8) through which air is expelled from the inner chamber of the bellows during compression." (Please see Column 3, Lines 9-15).
- 21. **As to Claim 21,** Sitnik discloses the bag to be formed of a resilient material that can be squeezed into compression so as to force gas from the inner closed cavity and released for decompression so as to draw gas into the inner closed cavity. Sitnik states, "the bag is constructed of materials which are moldable and are very resilient, such as a polyvinyl plastic or a polyurethane. The plates of the bellows are thick enough, in comparison to the pleats of the compressible walls, so as to act relatively rigid. Reinforcing ribs are added as required. The pleats are constructed sufficiently thick such that the bellows totally recovers to full inflation in less than four (4) seconds after being completely compressed." (Please see Column 2, Lines 32-43).

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22. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 23. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
  - 1. Determining the scope and contents of the prior art.
  - 2. Ascertaining the differences between the prior art and the claims at issue.
  - 3. Resolving the level of ordinary skill in the pertinent art.
  - 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 24. Claims 1-11, 18-20, 22-26, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sitnik (US 4,870,962) in view of Michielsen (US 3,575,167).
- 25. **As to Claim 1,** Sitnik discloses a respiratory system for the delivery of compressed gas to a patient comprising a face mask (16), a bellow system (1) having an input port (7) and an output port (8), and a gas conduit (13). (Please see Figures 1-3). Regarding the bellows (1), Sitnik discloses the bellows of the respiratory system to

be fully capable of being compressed by the user to allow the exportation of exhaust gas via the output port and resiliently expandable to draw gas from the input port. Sitnik states, "the bag (1) is fitted with an air (and/or oxygen) intake valve (7) through which air is drawn during its self-inflation portion of the pump cycle. There is an air (and/or oxygen) outlet (8) through which air is expelled from the inner chamber of the bellows during compression." (Please see Column 3, Lines 9-15). Regarding the conduit (13),

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Sitnik discloses the conduit to be interconnected with the output port and the mask. (Please see Figure 3). Sitnik discloses a respiratory system comprising all the limitations recited in Claim 1, with the exception of a harness. However, the use of a harness was known at the time the invention was made. Specifically, Michielsen teaches the use of a harness for the convenient and compact carrying of a respiratory device. Michielsen teaches a respiratory system for the delivery of compressed gas to a patient having a harness system (59 and 61) fully capable of allowing the user to compress the bellows in a hands free manner, while providing special attention to the face mask of the patient. The harness system consists of "rings (59) engaging with a suitable harness means (61) for carrying the apparatus on a user's body." (Please see Column 5, Lines 30-35). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the respiratory device of Stinik by adding a harness system because it is well known in the art, as taught by Michielsen to have a conveniently portable respiratory device in order to provide emergency assistance to patients.

26. **As to Claims 2 and 3,** Stinik discloses a respiratory system for the delivery of compressed gas to a patient comprising a gas source, compressed oxygen, to be coupled with the input port. Stinik states, "the bag can be connected to a regulated supply of oxygen (or another reservoir of oxygen) via an attachment that connects the air intake valve to the oxygen supply." (Please see Column 2, Lines 50-55). Stinik's disclosure eludes to the use of compressed gas as an oxygen source and thus comprising all the limitations as recited in **Claims 2 and 3.** Therefore, it would have

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been obvious to one having ordinary skill in the art at the time of invention to modify the teachings of Stinik to incorporate a compressed gas source.

- 27. **As to Claims 4 and 5,** the respiratory system of Stinik as modified by Michielsen is fully capable of being sized to maintain the bellow in a position where the user can compress the bellow between their upper arm and torso and contains shoulder straps for the support of the bellows. Further regarding the bellow shaped bag, Stinik discloses "its flat sides eliminate any tendency to roll away while being compressed, and thus enables an operator to compress it under his arm or knee, therein freeing both his hands for performing other tasks." (Please see Column 2, Lines 20-25). Stinik discloses a respiratory device comprising all the limitations recited in **Claims 4 and 5**. Therefore, it would have been obvious, if not inherent, to one having ordinary skill in the art at the time of invention to modify the system of Stinik as modified by Michielsen to enable compression of the bellow via the user's upper arm and torso.
- 28. As to Claim 6, the respiratory system of Stinik as modified by Michielsen is fully capable of resting on the shoulder of the user and providing support to the bellow. Regarding the bellow shaped bag, Stinik discloses "its flat sides eliminate any tendency to roll away while being compressed, and thus enables an operator to compress it under his arm or knee, therein freeing both his hands for performing other tasks." (Please see Column 2, Lines 20-25). Further, Figures 3 and 5 disclose the strap configuration and placement on the user. Stinik discloses a respiratory device comprising all the limitations recited in Claim 6. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to modify the system of Stinik and

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Michielsen to enable compression of the bellow via the user's upper arm and torso, while the shoulders of the user are supporting the bellow.

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- 29. **As to Claim 7,** Stinik discloses a respiratory system comprising all the limitations recited in **Claim 7,** but does not expressly disclose two bellows. At the time in which the invention was made, a two bellow system would provide the user additional control in during the respiratory process. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to have a two bellow system as the Applicant has done. Moreover, Applicant has not asserted that the specific two bellow system recited provides a particular advantage, solves a stated problem, or serves a purpose different from that of providing additional control during the respiratory process, thus the use of the two bellow system lacks criticality in its design.
- 30. As to Claims 8 and 9, the respiratory system of Stinik as modified by Michielsen is fully capable of being sized to maintain the bellow in a position where the user can compress the bellow between their upper arm and torso and contains shoulder straps for the support of the bellows. Further regarding the bellow shaped bag, Stinik discloses "its flat sides eliminate any tendency to roll away while being compressed, and thus enables an operator to compress it under his arm or knee, therein freeing both his hands for performing other tasks." (Please see Column 2, Lines 20-25). Sitnik discloses a respiratory device comprising all the limitations recited in Claim 8, 9, and 10, with the exception of a two bellow system. At the time in which the invention was made, a two bellow system would provide the user additional control in during the respiratory process. Therefore, it would have been obvious to one having ordinary skill

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in the art at the time of the invention to have a two bellow system as the Applicant has done. Moreover, Applicant has not asserted that the specific two bellow system recited provides a particular advantage, solves a stated problem, or serves a purpose different from that of providing additional control during the respiratory process, thus the use of the two bellow system lacks criticality in its design.

31. As to Claim 10, the respiratory system of Stinik as modified by Michielsen is fully capable of resting on the shoulder of the user and providing support to the bellow. Regarding the bellow shaped bag. Stinik discloses "its flat sides eliminate any tendency to roll away while being compressed, and thus enables an operator to compress it under his arm or knee, therein freeing both his hands for performing other tasks." (Please see Column 2, Lines 20-25). Further, Figures 3 and 5 disclose the strap configuration and placement on the user. Sitnik discloses a respiratory device comprising all the limitations recited in Claim 8, 9, and 10, with the exception of a two bellow system. At the time in which the invention was made, a two bellow system would provide the user additional control in during the respiratory process. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to have a two bellow system as the Applicant has done. Moreover, Applicant has not asserted that the specific two bellow system recited provides a particular advantage, solves a stated problem, or serves a purpose different from that of providing additional control during the respiratory process, thus the use of the two bellow system lacks criticality in its design.

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32. As to Claims 18, 19, 20, and 30, Sitnik discloses a respiratory device comprising all the limitations recited in Claims 18, 19, 20, and 30, with the exception of a harness with a locking device. However, the use of a harness and locking device was well known at the time the invention was made. Specifically, Michielsen teaches the use of a harness with a locking device for the convenient and compact carrying of a respiratory device. Michielsen teaches a respiratory system for the delivery of compressed gas to a patient having a harness system (59 and 61) fully capable of allowing the user to compress the bellows in a hands free manner, while providing special attention to the face mask of the patient. The harness system consists of "rings (59) engaging with a suitable harness means (61) for carrying the apparatus on a user's body." (Please see Column 5, Lines 30-35). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the respiratory device of Stinik by adding a harness system because it is well known in the art, as taught by Michielsen to have a conveniently portable respiratory device in order to provide emergency to patients.

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33. As to Claim 22, Sitnik discloses a respiratory system for the delivery of compressed gas to a patient comprising a face mask (16), a bellow (1) having an input port (7) and an output port (8), and a gas conduit (13). (Please see Figures 1-3). Regarding the bellows (1), Sitnik discloses the bellows of the respiratory system to be fully capable of being compressed by the user to allow the exportation of exhaust gas via the output port and resiliently expandable to draw gas from the input port. Sitnik states, "the bag (1) is fitted with an air (and/or oxygen) intake valve (7) through which air

is drawn during its self-inflation portion of the pump cycle. There is an air (and/or oxygen) outlet (8) through which air is expelled from the inner chamber of the bellows during compression." (Please see Column 3, Lines 9-15). Regarding the conduit (13), Sitnik discloses the conduit to be interconnected with the output port and the mask. (Please see Figure 3). Sitnik discloses a respiratory system comprising all the limitations recited in Claim 22, with the exception of a harness and a first and second bellow. Regarding the harness, the use of a harness was known at the time the invention was made. Specifically, Michielsen teaches the use of a harness for the convenient and compact carrying of a respiratory device. Michielsen teaches a respiratory system for the delivery of compressed gas to a patient having a harness system (59 and 61) fully capable of allowing the user to compress the bellows in a hands free manner, while providing special attention to the face mask of the patient. The harness system consists of "rings (59) engaging with a suitable harness means (61) for carrying the apparatus on a user's body." (Please see Column 5, Lines 30-35). Regarding the first and second bellows, the system of Stinik as modified by Michielsen does not expressly disclose a two bellows system. However, at the time in which the invention was made, a two bellow system would provide the user additional control in during the respiratory process. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to modify the respiratory device of Stinik by adding a harness system and a two bellow system, to provide emergency assistance to patients. Moreover, Applicant has not asserted that the specific two

bellow system recited provides a particular advantage, solves a stated problem, or

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serves a purpose different from that of providing additional control during the respiratory process, thus the use of the two bellow system lacks criticality in its design.

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- 34. **As to Claims 23-26**, Stinik discloses a respiratory system comprising all the limitations recited in **Claims 23-26**, but does not expressly disclose two bellows. Stinik discloses "the flat sides [of the bellow] eliminate any tendency to roll away while being compressed, and thus enables an operator to compress it under his arm or knee, therein freeing both his hands for performing other tasks." (Please see Column 2, Lines 20-25). At the time in which the invention was made, a two bellow system would provide the user additional control in during the respiratory process. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to have a two bellow system as the Applicant has done. Moreover, Applicant has not asserted that the specific two bellow system recited provides a particular advantage, solves a stated problem, or serves a purpose different from that of providing additional control during the respiratory process, thus the use of the two bellow system lacks criticality in its design.
- 35. As to Claims 27-29, the respiratory system of Stinik as modified by Michielsen has a harness system that consists of two straps that are places around the users' torso and connected to the bellow device in the front of the user. As shown in Figure 5, the harness straps cross at the back of the user and connect at the front of the user to secure the bellow system to the torso of the user. The detachable nature of the locking strap system, allows the user to wear and remove the respiratory device. The system of Stinik as modified by Michielsen comprise all the limitations recited in Claims 27-29,

but does not expressly disclose two bellows. At the time in which the invention was made, a two bellow system would provide the user additional control in during the respiratory process. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to have a two bellow system as well as the harness strapping system as the Applicant has done. Moreover, Applicant has not asserted that the specific two bellow system recited provides a particular advantage, solves a stated problem, or serves a purpose different from that of providing additional control during the respiratory process, thus the use of the two bellow system lacks criticality in its design.

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## Conclusion

36. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The balance of art listed by US patent number below, shows additional inventions in the field of devices capable of providing emergency air delivery. US Patents: 4,752,263; 5,092,327; 3,536,071; 1,177,208; 5,203,325

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette F. Dixon whose telephone number is (571) 272-3392. The examiner can normally be reached on Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Annette F Dixon Examiner Art Unit 3743 February 21, 2006

AFD

Supervisory Patent Examiner